

**REMARKS**

**I. Interview With Examiner Bui**

Applicant gratefully acknowledges the Examiner's grant of a telephone interview on November 7, 2005, at which time the amended claim was discussed. During the interview, the Examiner agreed that the stent of Mathis is in the martensitic state in its restrained shape and indicated that the amendment would advance prosecution by distinguishing the present claims over the Mathis reference, which does not teach a medical device having an at least partially deformed shape memory element in an austenitic state in its restrained shape.

**II. Status of the Claims**

Claims 14-24 are pending. Claims 14, 19, and 21 have been amended. Claim 14 has been amended to rephrase and simplify the claim language. Support for the specific language used in claim 14 can be found in the specification, which discloses that "[t]he shape memory alloy is heated to a temperature at or above  $M_d$  where the alloy is at least partially deformed into a restrained shape while in an austenitic state." See Specification at page 5, lines 14-16. The specification further states that "[t]he medical device is positioned at least partially inside the hollow delivery system to hold the shape-memory alloy in the restrained shape." *Id.* at page 5, lines 16-18. Claims 19 and 21 have been amended to correct obvious typographical errors. No new matter has been added.

III. 102(e)/103 Rejection

The Examiner has maintained the rejection of claims 14-24 under 35 U.S.C. §§ 102(e)/103 as being anticipated by, or in the alternative, obvious in view of U.S. Patent No. 6,129,755 to Mathis et al. ("Mathis"). See Advisory Action at 2 and Final Office Action at 2-3. Applicants continue to disagree and traverse these rejections for the reasons of record, and the following additional reasons.

To anticipate a claim under 35 U.S.C. § 102, the reference must teach every element of the claim. M.P.E.P. § 2131; *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."). To establish a *prima facie* case of obviousness under 35 U.S.C. § 103, the prior art must suggest the desirability of the claimed invention. M.P.E.P. § 2143.01.

With regard to claim 14, the Examiner alleges that "[t]he unrestrained portion free from sheath 40 is heated by the body temperature to a temperature in the range of 24-37 degree Celsius to be transformed into an austenite state as recited in the claim." Final Office Action at page 2. In the Advisory Action, the Examiner further alleged:

When self-expanding Nitinol Mathis-'755 stent 50 partially deployed from sheath 40, stent 50 is partially constrained or deformed because a portion of stent 50 is still constrained in sheath 40 while a portion of stent 50 is expanded and exposed to the patient body temperature. The austenite finish temperature of stent 50 is in a range of 24-37 degrees C, therefore at least a portion of stent 50 deployed outside sheath 40 and directly exposed to body temperature of about 36 degrees C will transform into an austenite state. In this condition, at least stent 50 meets the language of independent claim 1 [sic].

Advisory Action at 2.

Based on the Examiner's statements in the Advisory Action, Applicant respectfully submits that the Examiner incorrectly and improperly applied the teachings of Mathis to the present claims, including claim 14, which recites "a hollow delivery system holding the at least partially deformed shape memory alloy element **in an austenitic phase in its restrained shape.**"

In direct contrast, Mathis clearly teaches that "the stent is then cooled until it is completely martensitic, crimped down to its un-expanded diameter and then loaded into the sheath of the delivery apparatus." Mathis at col. 9, lines 5-7. In other words, the stent of Mathis **is in a martensitic state in its restrained shape.**

The Examiner has not only misconstrued the present claims, but has also made unsupported assertions regarding the teaching of Mathis. For example, according to the Examiner, the stent of Mathis anticipates the present claims because the deployed portion of the Mathis stent is allegedly in the austenitic state. Advisory Action at 2. In other words, the Examiner is improperly rejecting the claimed invention which describes an austenite state in a **restrained shape** over the teachings of Mathis, which describes an austenite state in a **deployed shape.**

Moreover, the Examiner has provided no evidence to support the assertion that the partially deployed portion of the Mathis stent will transform into an austenitic state. In fact, in the "Background of the Invention" section, Mathis discusses the characteristics of shape memory alloys and discloses that "heating of the deformed martensite phase to a temperature above the martensite to austenite transformation temperature causes the deformed martensite phase to transform to the austenite

phase,” but that “[i]f restrained, the metal will remain martensitic until the restraint is removed.” Mathis at col. 2, lines 49-65. Mathis is silent as to the transformation mechanics of the stent as it is deployed. Thus, the Examiner’s assertion that the deployed portion transforms to an austenitic state is an unsupported assertion that directly contradicts Mathis, which teaches that “the metal will remain martensitic until the restraint is removed.” *Id.* Because even the alleged partially deformed stent of Mathis is still restrained by the sheath, the Examiner has failed to support the assertion that the partially deployed portion of the Mathis stent transforms to the austenite state.

The Examiner alleges, in the alternative, that the present claims are obvious over Mathis. As explained above, to establish a *prima facie* case of obviousness, the prior art must suggest the desirability of the claimed invention. M.P.E.P. § 2143.01.

Mathis clearly teaches away from a shape memory alloy medical device in an austenitic state in a restrained shape because Mathis discloses that the stent is cooled until it is completely martensitic before it is deformed and restrained, and that the stent does not transform to the austenite state until the restraint is removed. As the prior art teaches away from the claimed invention, the requisite desirability or motivation to modify Mathis to obtain the claimed invention cannot present. See, *In re Laskowski*, 10 USPQ 2d 1397 (Fed. Cir. 1989). The Examiner’s attention is also directed to well-known Federal Circuit decisions holding that if a proposal for modifying the prior art in an effort to attain the claimed invention causes the art to become inoperable or destroys its intended function, then the requisite motivation to make the modification would not have existed. See, *In re Fritch*, 972 F.2d 1260, 1265-66, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992); *In re Ratti*, 270 F.2d 810, 813, 123 U.S.P.Q. 349, 352 (C.C.P.A. 1959).

Thus, Mathis does not teach or suggest a medical device and delivery system having the elements recited in the present claims because Mathis does not teach a shape memory alloy element being in an austenitic state when in an at least partially deformed configuration in its restrained shape. In fact, Mathis teaches away from the claimed invention because Mathis requires the stent to be in the martensitic state before it is restrained, a state in which Mathis clearly teaches the stent remains until the restraint is removed.

For at least the foregoing reasons, Applicant submits that the rejections over Mathis are improper and should be withdrawn.

#### IV. Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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